AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.730 Standards for Stroke Center Designation

PURPOSE: This rule establishes standards for level I, II, III, and IV stroke center designation.

AGENCY NOTE:
I-R, II-R, III-R, or IV-R after a standard indicates a requirement for level I, II, III, or IV stroke centers respectively.
I-IH, II-IH, III-IH, or IV-IH after a standard indicates an in-house requirement for level I, II, III, or IV stroke centers respectively.
I-IA, II-IA, III-IA, or IV-IA indicates an immediately available requirement for level I, II, III, or IV stroke centers respectively.
I-PA, II-PA, III-PA, or IV-PA indicates a promptly available requirement for level I, II, III, or IV stroke centers respectively.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome and expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) General Standards for Stroke Center Designation.

(A) The stroke center board of directors, administration, medical staff, and nursing staff shall demonstrate a commitment to quality stroke care. Methods of demonstrating the commitment shall include, but not be limited to, a board resolution that the hospital governing body agrees to establish policy and procedures for the maintenance of services essential for a stroke center; assure that all stroke patients will receive medical care at the level of the hospital's designation; commit the institution's financial, human, and physical resources as needed for the stroke program; and establish a priority admission for the stroke patient to the full services of the institution. (I-R, II-R, III-R, IV-R)

(B) Stroke centers shall agree to accept all stroke patients appropriate for the level of care provided at the hospital, regardless of race, sex, creed, or ability to pay. (I-R, II-R, III-R, IV-R)

(C) The stroke center shall demonstrate evidence of a stroke program. The stroke program shall be available twenty-four (24) hours a day, seven (7) days a week to evaluate and treat stroke patients. (I-R, II-R, III-R, IV-R)

1. The stroke center shall maintain a stroke team that at a minimum shall consist of—

A. A core team which provides administrative oversight and includes:

(I) A physician experienced in diagnosing and treating cerebrovascular disease (usually the stroke medical director); and (I-R, II-R, III-R, IV-R)

(II) At least one (1) other health care professional or qualified individual credentialed in stroke patient care (usually the stroke program manager/coordinator); (I-R, II-R, III-R, IV-R)

B. A stroke call roster that provides twenty-four (24) hours a day, seven (7) days a week neurology service coverage. The call roster identifies the physicians or qualified individuals on the schedule that are available to manage and coordinate emergent, urgent, and routine assessment, diagnosis, and treatment of stroke patients. A level I stroke center call roster shall include, but not be limited to, the emergency department physician, neuro-interventionalist, neurologist, and others as appropriate. A level II stroke center call roster shall include, but not be limited to, the emergency department physician, a physician with experience and expertise in diagnosing and treating patients with cerebrovascular disease, and others as appropriate. The level III stroke center call roster shall include, but not be limited to, the emergency department physician and others as appropriate. A level IV stroke center call roster shall include, but not be limited to, the emergency department physician and other qualified individuals as appropriate. (I-R, II-R, III-R, IV-R)

(I) This coverage shall be available from notification of stroke patients according to the response requirements as set out below—

(a) Level I and II stroke centers shall have this coverage available within fifteen (15) minutes of notification of a stroke patient; and (I-R, II-R)

(b) Level III and IV stroke centers shall have a regional networking agreement with a level I or level II stroke center for telephone consult or telemedicine consultation available within fifteen (15) minutes of notification of a stroke patient; and (III-R, IV-R)

C. A clinical team appropriate to the center level designation that may include, but not be limited to, members of the stroke call roster, neurologists, physicians with expertise caring for stroke patients, neuro-interventionalists, neurosurgeons, anesthesiologists, intensivists, emergency department physicians, and other stroke center clinical staff as applicable. (I-R, II-R, III-R, IV-R)

2. The stroke center shall have a peer review system to review stroke cases respective of the stroke center's designation. (I-R, II-R, III-R, IV-R)

3. The stroke team members shall have appropriate experience to maintain skills and proficiencies to care for stroke patients. The stroke center shall maintain evidence that it meets the following requirements by documenting the following:

A. A list of all stroke team members; (I-R, II-R, III-R, IV-R)

B. Position qualifications and completion of continuing education requirements by stroke team members as set forth in sections (1), (2), and (4) of this rule; (I-R, II-R, III-R, IV-R)

C. Management of sufficient numbers of stroke patients by the stroke team members in order to maintain their stroke skills; (I-R, II-R, III-R, IV-R)

D. Participation by the core team and members of the stroke call roster in at least half of the regular, ongoing stroke program peer review system meetings as shown in meeting attendance documents. The stroke medical director shall disseminate the information and findings from the peer review system meetings to the stroke call roster members and the core team and document such dissemination; (I-R, II-R, III-R, IV-R)

E. Participation by stroke team members in at least half of the regular, ongoing stroke program performance improvement and patient safety meetings and documentation of such attendance in the meeting minutes and/or meeting attendance documents. The stroke medical director shall disseminate the information and findings from the performance improvement and patient safety meetings to the stroke team members and document such dissemination. If a stroke team member is unable to attend a stroke program performance improvement and patient safety meeting, then the stroke team member shall send an appropriate representative in his/her place; (I-R, II-R, III-R, IV-R)

F. Maintenance of skill levels in the management of stroke patients by the stroke team members as required by the stroke center and the stroke medical director and documentation of such continued experience; (I-R,

II-R, III-R, IV-R)

G. Review of regional outcome data on quality of patient care by the stroke team members as part of the stroke center's performance improvement and patient safety process; and (I-R, II-R, III-R, IV-R)

H. Evidence of a written agreement between a level III stroke center and a level I or II stroke center when a level III stroke center has a supervised relationship with a physician affiliated with a level I or II stroke center. A level III stroke center which provides lytic therapy to stroke patients may have an established plan for admitting and caring for stroke patients under a supervised relationship with a physician affiliated with a level I or II stroke center. This supervised relationship shall consist of a formally established and pre-planned relationship between the centers in which a physician from a level I or level II center supervises a physician in a level III center in the evaluation of a stroke patient for lytic therapy and the care of the patient post-lytic therapy in certain circumstances where that level III center does not transfer the patient to a higher level stroke center. In this setting, management decisions, including, but not limited to, administration of lytic therapy, transfer or non-transfer of patient, and post-lytic therapy shall be made jointly between the supervising and supervised physicians. Care protocols and pathways for patients that fall into this category shall be established by both parties at the outset of the establishment of the relationship. This supervised relationship shall be established by written agreement and detail the supervision of patient care. This written agreement may also include, but not be limited to, observation of patient care, review of level III stroke center's patient encounters, review of level III center's outcomes, evaluation of the level III center's process pertaining to stroke patients, and lytic therapy and guidance on methods to improve process, performance, and outcomes.

4. The stroke center shall maintain a multidisciplinary team, in addition to the stroke team, to support the care of stroke patients. (I-R, II-R, III-R, IV-R)

A. The multidisciplinary team shall include a suitable representative from hospital units as appropriate for care of each stroke patient. The hospital units represented on the multidisciplinary team may include, but not be limited to: administration, emergency medical services, intensive care unit, radiology, pharmacy, laboratory, stroke unit, stroke rehabilitation, and discharge planning. (I-R, II-R, III-R, IV-R)

B. The multidisciplinary team members or their representatives shall attend at least half of the stroke program performance improvement and patient safety program meetings which shall be documented in the meeting minutes and/or meeting attendance documents. (I-R, II-R, III-R, IV-R)

(D) A level I stroke center shall provide the services of a neuro-interventional laboratory staffed twenty-four (24) hours a day, seven (7) days a week.

1. The staff of the neuro-interventional laboratory, referred to as the neuro-interventional laboratory team, shall consist of at least the following:

A. Neuro-interventional specialist(s); and (I-R/PA)

B. Other clinical staff as deemed necessary. (I-R/PA)

2. The stroke center neuro-interventional laboratory team shall maintain core competencies annually as required by the stroke center. (I-R/PA)

3. The hospital credentialing committee shall document that the neuro-interventional specialist(s) have completed appropriate training and conducted sufficient neuro-interventional procedures. (I-R/PA)

4. The stroke center neuro-interventional laboratory team shall remain up to date in their continuing education requirements which are set forth in section (4) of this rule. (I-R/PA)

5. Resuscitation equipment shall be available in the neuro-interventional lab. (I-R)

(E) It is recommended that a level I stroke center meet the volume for stroke patient cases that is required for eligibility by The Joint Commission in its Advanced Certification of Comprehensive Stroke Centers as posted on January 31, 2012, which is incorporated by reference in this rule and is available at The Joint Commission, One Renaissance Boulevard, Oakbrook Terrace, IL 60181 or on The Joint Commission's website at www.jointcommission.org. This rule does not incorporate any subsequent amendments or additions.

(F) The stroke center shall appoint a physician to serve as the stroke medical director. A stroke medical director shall be appointed at all times with no lapses. (I-R, II-R, III-R, IV-R)

1. A level I stroke medical director shall have appropriate qualifications, experience, and training. A board-certified or board-admissible neurologist or other neuro-specialty trained physician is recommended. If the stroke medical director is board-certified or board-admissible, then one (1) of the following additional qualifications shall be met and documented. If the stroke medical director is not board-certified, then two (2) of the following additional qualifications shall be met and documented:

A. Completion of a stroke fellowship; (I-R)

B. Participation (as an attendee or faculty) in one (1) national or international stroke course or conference each year or two (2) regional or state stroke courses or conferences each year; or (I-R)

C. Five (5) or more peer-reviewed publications on stroke. (I-R)

2. A level II stroke medical director shall have appropriate qualifications, experience, and training. A board-certified or board-admissible physician with training and expertise in cerebrovascular disease is recommended. If the stroke medical director is board-certified or board-admissible, then one (1) of the following additional qualifications shall be met. If the stroke medical director is not board-certified, then two (2) of the following additional qualifications shall be met and documented:

A. Completion of a stroke fellowship; (II-R)

B. Participation (as an attendee or faculty) in one (1) national or international stroke course or conference each year or two (2) regional or state stroke courses or conferences each year; or (II-R)

C. Five (5) or more peer-reviewed publications on stroke. (II-R)

3. A level III and IV stroke medical director shall have the appropriate qualifications, experience, and training. A board-certified or board-admissible physician is recommended. If the stroke medical director is not board-certified or board-admissible, then the following additional qualifications shall be met and documented:

A. Complete a minimum of ten (10) hours of continuing medical education (CME) in the area of cerebrovascular disease every other year; and (III-R, IV-R)

B. Attend one (1) national, regional, or state meeting every three (3) years in cerebrovascular disease. Continuing medical education hours earned at these meetings can count toward the ten (10) required continuing medical education hours. (III-R, IV-R)

4. The stroke medical director shall meet the department's continuing medical education requirements for stroke medical directors as set forth in section (4) of this rule. (I-R, II-R, III-R, IV-R)

5. The stroke center shall have a job description and organizational chart depicting the relationship between the stroke medical director and the stroke center services. (I-R, II-R, III-R, IV-R)

6. The stroke medical director is encouraged to be a member of the stroke call roster. (I-R, II-R, III-R, IV-R)

7. The stroke medical director shall be responsible for the oversight of the education and training of the medical and clinical staff in stroke care. This includes a review of the appropriateness of the education and training for the practitioner's level of responsibility. (I-R, II-R, III-R, IV-R)

8. The stroke medical director shall participate in the stroke center's research and publication projects. (I-R)

(G) The stroke center shall have a stroke program manager/coordinator who is a registered nurse or qualified individual. The stroke center shall have a stroke program manager/coordinator at all times with no lapses. (I-R, II-R, III-R, IV-R)

1. The stroke center shall have a job description and organizational chart depicting the relationship between the stroke program manager/coordinator and the stroke center services. (I-R, II-R, III-R, IV-R)

2. The stroke program manager/coordinator shall—

A. Meet continuing education requirements as set forth in section (4) of this rule; and (I-R, II-R, III-R, IV-R)

B. Participate in the performance improvement and patient safety program. (I-R, II-R, III-R, IV-R)

(H) The stroke center shall have a specific and well-organized system to notify and rapidly activate the stroke team to evaluate patients presenting at the stroke center with symptoms suggestive of an acute stroke. (I-R, II-R, III-R, IV-R)

(I) The stroke center shall have a one- (1-) call stroke team activation protocol. This protocol shall establish the following:

1. The criteria used to triage stroke patients shall include, but not be limited to, the time of symptom onset; (I-R, II-R, III-R, IV-R)

2. The persons authorized to notify stroke team members when a suspected stroke patient is in route and/or when a suspected stroke patient has arrived at the stroke center; (I-R, II-R, III-R, IV-R)

3. The method for immediate notification and the response requirements for stroke team members when a suspected stroke patient is in route to the stroke center and/or when a suspected stroke patient has arrived at the stroke center; and (I-R/IA, II-R/IA, III-R/IA, IV-R/IA)

4. All members of the stroke call roster shall comply with the availability and response requirements per the stroke center's protocols and be in communication within fifteen (15) minutes of notification of the patient. If not on the stroke center's premises, stroke call roster members who are on call shall carry electronic communication devices at all times to permit contact by the hospital. It is recommended that one (1) member of the stroke team, per stroke center protocol, be at the patient's bedside within fifteen (15) minutes of notification of the patient. (I-R, II-R, III-R, IV-R)

(J) The stroke center shall have a fibrinolysis protocol for cases when fibrinolysis is achievable. (I-R, II-R, III-R)

(K) The stroke center shall have transfer agreements between referring and receiving facilities that address the following:

1. A one- (1-) call transfer protocol that establishes the criteria used to triage stroke patients and identifies persons authorized to notify the designated stroke center; and (I-R, II-R, III-R, IV-R)

2. A rapid transfer process in place to transport a stroke patient to a higher level of stroke care when needed. (II-R, III-R, IV-R)

(L) The stroke center shall have rehabilitation services that are directed by a physician with board certification in physical medicine and rehabilitation or by other properly trained individuals (e.g., neurologist experienced in stroke rehabilitation). (I-R, II-R)

(M) The stroke center shall have consults for physical medicine and rehabilitation, physical therapy, occupational therapy, and speech therapy requested and completed when deemed medically necessary within forty-eight (48) hours of admission. (I-R, II-R)

(N) The stroke center shall demonstrate that there is a plan for adequate post-discharge and post-transfer follow-up on stroke patients, including rehabilitation and repatriation, if indicated. (I-R, II-R, III-R, IV-R)

(O) The stroke center shall maintain a stroke patient log. The log information shall be kept for a period of five (5) years and made available to the Department of Health and Senior Services (department) during reviews for all stroke patients which contains the following:

1. Response times; (I-R, II-R, III-R, IV-R)

2. Patient diagnosis; (I-R, II-R, III-R, IV-R)

3. Treatment/actions; (I-R, II-R, III-R, IV-R)

4. Outcomes; (I-R, II-R, III-R, IV-R)

5. Number of patients; and (I-R, II-R, III-R, IV-R)

6. Benchmark indicators. (I-R, II-R, III-R, IV-R)

(P) The stroke center shall have a helicopter landing area. (I-R, II-R, III-R, IV-R)

1. Level I and II stroke centers shall have a lighted designated helicopter landing area at the stroke center to accommodate incoming medical helicopters. (I-R, II-R)

A. The landing area shall serve solely as the receiving and take-off area for medical helicopters and shall be cordoned off at all times from the general public to assure its continual availability and safe operation. (I-R, II-R)

B. The landing area shall be on the hospital premises no more than three (3) minutes from the emergency room. (I-R, II-R)

2. Level III and IV stroke centers shall have a lighted designated helicopter landing area that meets the following requirements:

A. Accommodates incoming medical helicopters; (III-R, IV-R)

B. Serves as the receiving and take-off area for medical helicopters; (III-R, IV-R)

C. Be cordoned off when in use from the general public; (III-R, IV-R)

D. Be managed to assure its continual availability and safe operation; and (III-R, IV-R)

E. Though not required, it is recommended the landing area be no more than three (3) minutes from the emergency department. (III-R, IV-R)

(Q) Stroke centers shall enter data into the Missouri stroke registry as follows:

1. All stroke centers shall submit data into the department's Missouri stroke registry on each stroke patient who is admitted to the stroke center, transferred out of the stroke center, or dies as a result of the stroke (independent of hospital admission or hospital transfer status). The data required to be submitted into the Missouri stroke registry by the stroke centers is listed and explained in the document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" dated March 1, 2012, which is incorporated by reference in this rule and is available at the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or on the department's website at www.health.mo.gov. This rule does not incorporate any subsequent amendments or additions; (I-R, II-R, III-R, IV-R)

2. The data required in paragraph (1)(Q)1. above shall be submitted electronically into the Missouri stroke registry via the department's website at www.health.mo.gov; (I-R, II-R, III-R, IV-R)

3. The data required in paragraph (1)(Q)1. above shall be submitted electronically into the Missouri stroke registry on at least a quarterly basis for that calendar year. Stroke centers have ninety (90) days after the quarter ends to submit the data electronically into the Missouri stroke registry; (I-R, II-R, III-R, IV-R)

4. The data submitted by the stroke centers shall be complete and current; and (I-R, II-R, III-R, IV-R)

5. The data shall be managed in compliance with the confidentiality requirements and procedures contained in section 192.067, RSMo. (I-R, II-R, III-R, IV-R)

(R) A stroke center shall maintain a diversion protocol for the stroke center that is designed to allow best resource management within a given area. The stroke center shall create criteria for diversion in this diversion protocol and shall detail a performance improvement and patient safety process in the diversion protocol to review and validate the criteria for diversion created by the stroke center. The stroke center shall also collect, document, and maintain diversion information that includes at least the date, length of time, and reason for diversion. This diversion information shall be readily retrievable by the stroke center during a review by the department and shall be kept by the stroke center for a period of five (5) years. (I-R, II-R, III-R, IV-R)

(2) Medical Staffing Standards for Stroke Center Designation.

(A) The stroke center's medical staff credentialing committee shall provide a delineation of privileges for neurologists, neurosurgeons, and neuro-interventionalists, as applicable to the stroke center. (I-R, II-R)

(B) The stroke center shall credential and shall have the following types of physicians available as listed below:

1. A neurologist shall be available for consultation within fifteen (15) minutes of patient notification; (I-R)

2. A physician with experience and expertise in diagnosing and treating patients with cerebrovascular disease shall be available for consultation within fifteen (15) minutes of patient notification; (II-R)

3. A neurosurgeon as follows:

A. Neurosurgeon and back-up coverage on the call roster; (I-R/PA)

B. Neurosurgeon and back-up coverage on the call roster or available within two (2) hours by transfer agreement if not on staff; and (II-R/PA)

C. The neurosurgery staffing requirement may be fulfilled by a surgeon who has been approved by the chief of neurosurgery for care of stroke patients and shall be capable of initiating measures to stabilize the patient and perform diagnostic procedures; (I-R, II-R)

4. A neuro-interventional specialist; (I-R/PA)

5. An emergency department physician; (I-R/IH, II-R/IH, III-R/IH; IV-R/IA)

6. An internal medicine physician; (I-R/PA, II-R/PA, III-R/PA)

7. A diagnostic radiologist; and (I-R/IA, II-R/IA, III-R/IA)

8. An anesthesiologist. (I-R/PA, II-R/PA)

A. Anesthesiology staffing requirements may be fulfilled by anesthesiology residents, certified registered nurse anesthetists (CRNA), or anesthesia assistants capable of assessing emergent situations in stroke patients and of providing any indicated treatment including induction of anesthesia. When anesthesiology residents or CRNAs are used to fulfill availability requirements, the staff anesthesiologist on call will be advised and promptly available and present for all operative interventions and emergency airway conditions. The CRNA may proceed with life preserving therapy while the anesthesiologist is in route under the direction of the neurosurgeon, including induction of anesthesia. An anesthesiologist assistant shall practice only under the direct supervision of an anesthesiologist who is physically present or immediately available as this term is defined in section 334.400, RSMo. (I-R, II-R)

(3) Standards for Hospital Resources and Capabilities for Stroke Center Designation.

(A) The stroke center shall meet emergency department standards listed below. (I-R, II-R, III-R, IV-R)

1. The emergency department staffing shall meet the following requirements:

A. The emergency department in the stroke center shall provide immediate and appropriate care for the stroke patient; (I-R, II-R, III-R, IV-R)

B. A level I stroke center shall have a medical director of the emergency department who shall be board-certified or board-admissible in emergency medicine by the American Board of Medical Specialties, the American Osteopathic Association Board of Osteopathic Specialists, or the Royal College of Physicians and Surgeons of Canada; (I-R)

C. A level II stroke center shall have a medical director of the emergency department who shall be a board-certified or board-admissible physician; (II-R)

D. A level III and IV stroke center shall have a medical director of the emergency department who is recommended to be a board-certified or board-admissible physician; (III-R, IV-R)

E. There shall be an emergency department physician credentialed for stroke care by the stroke center covering the emergency department twenty-four (24) hours a day, seven (7) days a week; (I-R/IH, II-R/IH, III-R/IH, IV-R/IA)

F. The emergency department physician who provides coverage shall be current in continuing medical education in the area of cerebrovascular disease; (I-R, II-R, III-R, IV-R)

G. There shall be a written policy defining the relationship of the emergency department physicians to other physician members of the stroke team; (I-R, II-R, III-R, IV-R)

H. Registered nurses in the emergency department shall be current in continuing education requirements as set forth in section (4) of this rule; (I-R, II-R, III-R, IV-R)

I. All registered nurses assigned to the emergency department shall be determined to be credentialed in the care of the stroke patient by the stroke center within one (1) year of assignment and remain current in continuing education requirements as set forth in section (4) of this rule; and (I-R, II-R, III-R, IV-R)

J. The emergency department in stroke centers shall have written care protocols for identification, triage, and treatment of acute stroke patients that are available to emergency department personnel, reviewed annually, and revised as needed. (I-R, II-R, III-R, IV-R)

2. Nursing documentation for the stroke patient shall be on a stroke flow sheet approved by the stroke medical director and the stroke program coordinator/manager. (I-R, II-R, III-R, IV-R)

3. The emergency department shall have at least the following equipment for resuscitation and life support available to the unit:

A. Airway control and ventilation equipment including:

(I) Laryngoscopes; (I-R, II-R, III-R, IV-R)

(II) Endotracheal tubes; (I-R, II-R, III-R, IV-R)

(III) Bag-mask resuscitator; (I-R, II-R, III-R, IV-R)

(IV) Sources of oxygen; and (I-R, II-R, III-R, IV-R)

(V) Mechanical ventilator; (I-R, II-R, III-R)

B. Suction devices; (I-R, II-R, III-R, IV-R)

C. Electrocardiograph (ECG), cardiac monitor, and defibrillator; (I-R, II-R, III-R, IV-R)

D. Central line insertion equipment; (I-R, II-R, III-R)

E. All standard intravenous fluids and administration devices including intravenous catheters and intraosseous devices; (I-R, II-R, III-R, IV-R)

F. Drugs and supplies necessary for emergency care; (I-R, II-R, III-R, IV-R)

G. Two- (2-) way communication link with emergency medical service (EMS) vehicles; (I-R, II-R, III-R, IV-R)

H. End-tidal carbon dioxide monitor; and (I-R, II-R, III-R, IV-R)

I. Temperature control devices for patient and resuscitation fluids. (I-R, II-R, III-R IV-R)

4. The stroke center emergency department shall maintain equipment following the hospital's preventive maintenance schedule and document when this equipment is checked. (I-R, II-R, III-R, IV-R)

(B) The stroke center shall have a designated intensive care unit (ICU). (I-R, II-R)

1. The intensive care unit shall ensure staffing to provide appropriate care of the stroke patient. (I-R, II-R)

A. The stroke center intensive care unit shall have a designated intensive care unit medical director who has twenty-four (24) hours a day, seven (7) days a week access to a physician knowledgeable in stroke care and who meets the stroke call roster continuing medical education requirements as set forth in section (4) of this rule. (I-R, II-R)

B. The stroke center intensive care unit shall have a physician on duty or available twenty-four (24) hours a day, seven (7) days a week who is not the emergency department physician. This physician shall have access to a physician on the stroke call roster. (I-R/IA, II-R/IA)

C. The stroke center intensive care unit shall have a one to one (1:1) or one to two (1:2) registered nurse/patient ratio used for critically ill patients requiring intensive care unit level care. (I-R, II-R)

D. The stroke center intensive care unit shall have registered nurses in the intensive care unit who are current in continuing education requirements as set forth in section (4) of this rule. (I-R, II-R)

E. The stroke center intensive care unit shall have registered nurses in the intensive care unit who meet at least the following core credentials for care of stroke patients on a yearly basis:

(I) Care of patients after thrombolytic therapy; (I-R, II-R)

(II) Treatment of blood pressure abnormalities with parenteral vasoactive agents; (I-R, II-R)

(III) Management of intubated/ventilated patients; (I-R, II-R)

(IV) Detailed neurologic assessment and scales (e.g., National Institutes of Health Stroke Scale, Glasgow Coma Scale); (I-R, II-R)

(V) Care of patients with intracerebral hemorrhage and subarachnoid hemorrhage at all level I centers and all level II centers with neurosurgical capability; (I-R, II-R)

(VI) Function of ventriculostomy and external ventricular drainage apparatus in all level I centers and all level II centers with neurosurgical capability; and (I-R, II-R)

(VII) Treatment of increased intracranial pressure in all level I centers and all level II centers with neurosurgical capability. (I-R, II-R)

2. The stroke center intensive care unit shall have written care protocols for identification and treatment of acute stroke patients which are available to intensive care unit personnel, reviewed annually, and revised as needed. (I-R, II-R)

3. The stroke center intensive care unit shall have intensive care unit beds for stroke patients or, if space is not available in the intensive care unit, the stroke center shall make arrangements to provide the comparable level of care until space is available in the intensive care unit. (I-R, II-R)

4. The stroke center intensive care unit shall have equipment available for resuscitation and to provide life support for the stroke patient. This equipment shall include at least the following:

A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, and a mechanical ventilator; (I-R, II-R)

B. Oxygen source with concentration controls; (I-R, II-R)

C. Cardiac emergency cart, including medications; (I-R, II-R)

D. Telemetry, ECG capability, cardiac monitor, and defibrillator; (I-R, II-R)

E. Electronic pressure monitoring and pulse oximetry; (I-R, II-R)

F. End-tidal carbon dioxide monitor; (I-R, II-R)

G. Patient weighing devices; (I-R, II-R)

H. Drugs, intravenous fluids, and supplies; and (I-R, II-R)

I. Intracranial pressure monitoring devices. (I-R, II-R)

5. The intensive care unit shall check all equipment according to the hospital preventive maintenance schedule and the stroke center shall document when it is checked. (I-R, II-R)

(C) Level I and level II stroke centers shall provide a stroke unit. A level III stroke center that has an established plan for admitting and caring for stroke patients under a supervised relationship with a level I or II stroke center pursuant to subparagraph (1)(C)3.H. above shall also provide a stroke unit. (I-R, II-R, III-R)

1. The stroke center shall have a designated medical director for the stroke unit who has access to a physician knowledgeable in stroke care and who meets the stroke call roster continuing medical education requirements as set forth in section (4) of this rule. (I-R, II-R, III-R)

2. The stroke center stroke unit shall have a physician on duty or available twenty-four (24) hours a day, seven (7) days a week who is not the emergency department physician. This physician shall have access to a physician on the stroke call roster. (I-R/IA, II-R/IA, III-R/IA)

3. The stroke center stroke unit shall have registered nurses and other essential personnel on duty twenty-four (24) hours a day, seven (7) days a week. (I-R, II-R, III-R)

4. The stroke center stroke unit shall have registered nurses who are current in continuing education requirements as set forth in section (4) of this rule. (I-R, II-R, III-R)

5. The stroke center stroke unit shall annually credential registered nurses that work in the stroke unit. (I-R, II-R, III-R)

6. The stroke center stroke unit shall have written care protocols for identification and treatment of acute stroke patients (e.g., lytic and post-lytic management, hemorrhagic conversion according to current best evidence) which are available to stroke unit personnel, reviewed annually, and revised as needed. (I-R, II-R, III-R)

7. The stroke center stroke unit shall have equipment to support the care and resuscitation of the stroke patient that includes at least the following:

A. Airway control and ventilation equipment including:

(I) Laryngoscopes, endotracheal tubes of all sizes; (I-R, II-R, III-R)

(II) Bag-mask resuscitator and sources of oxygen; and (I-R, II-R, III-R)

(III) Suction devices; (I-R, II-R, III-R)

B. Telemetry, electrocardiograph, cardiac monitor, and defibrillator; (I-R, II-R, III-R)

C. All standard intravenous fluids and administration devices and intravenous catheters; and (I-R, II-R, III-R)

D. Drugs and supplies necessary for emergency care. (I-R, II-R, III-R)

8. The stroke center stroke unit shall maintain equipment following the hospital preventive maintenance schedule and document when it is checked. (I-R, II-R, III-R)

(D) The stroke center shall provide radiological and diagnostic capabilities. (I-R, II-R, III-R)

1. The radiological and diagnostic capabilities shall include a documented mechanism for prioritization of stroke patients and timely interpretation to aid in patient management. (I-R, II-R, III-R)

2. The radiological and diagnostic capabilities shall include the following equipment and staffing capabilities:

A. Angiography with interventional capability available twenty-four (24) hours a day, seven (7) days a week; (I-R/PA)

B. Cerebroangiography technologist on call and available within thirty (30) minutes for emergent procedures, and on call and available within sixty (60) minutes for routine procedures, and available twenty-four (24) hours a day, seven (7) days a week; (I-R)

C. In-house computerized tomography; (I-R/IA, II-R/IA, III-R/IA)

D. Computerized tomography perfusion; (I-R/IA)

E. Computerized tomography angiography; (I-R/IA)

F. Computerized tomography technologist; (I-R/IH, II-R/IH, III-R/IA)

G. Magnetic resonance imaging; (I-R, II-R)

H. Magnetic resonance angiogram/magnetic resonance venography; (I-R, II-R)

I. Magnetic resonance imaging technologist on call and available within sixty (60) minutes, twenty-four (24) hours a day, seven (7) days a week; (I-R, II-R)

J. Extracranial ultrasound; (I-R, II-R)

K. Equipment and clinical staff to evaluate for vasospasm available within thirty (30) minutes for emergent evaluation, and available within sixty (60) minutes for routine evaluation, and available twenty-four (24) hours a day, seven (7) days a week; (I-R)

L. Transthoracic echo; (I-R, II-R)

M. Transesophageal echo; and (I-R, II-R)

N. Resuscitation equipment available to the radiology department. (I-R, II-R, III-R)

3. The radiological and diagnostic capabilities shall include adequate physician and nursing personnel available with monitoring equipment to fully support the acute stroke patient and provide documentation of care during the time the patient is physically present in the radiology department and during transportation to and from the radiology department. (I-R, II-R, III-R)

4. The radiological and diagnostic capabilities shall include the stroke center maintaining all radiology and diagnostic equipment according to the hospital preventive maintenance schedule and documenting when it is checked. (I-R, II-R, III-R)

(E) All level I stroke centers shall have operating room personnel, equipment, and procedures. Those level II stroke centers with neurosurgical capability shall also meet operating room personnel, equipment, and procedure requirements. (I-R, II-R)

1. Operating room staff shall be available twenty-four (24) hours a day, seven (7) days a week. (I-R/PA, II-R/PA)

2. Registered nurses shall annually maintain core competencies as required by the stroke center.

3. Operating rooms shall have at least the following equipment:

A. Operating microscope; (I-R, II-R)

B. Thermal control equipment for patient and resuscitation fluids; (I-R, II-R)

C. X-ray capability; (I-R, II-R)

D. Instruments necessary to perform an open craniotomy; (I-R, II-R)

E. Monitoring equipment; and (I-R, II-R)

F. Resuscitation equipment available to the operating room. (I-R, II-R)

4. The operating room shall maintain all equipment according to the hospital preventive maintenance schedule and document when it is checked. (I-R, II-R)

(F) All level I stroke centers shall meet post-anesthesia recovery room (PAR) requirements listed below. Those level II stroke centers with neurosurgical capability shall also have a post-anesthesia recovery room and meet the requirements below—

1. The stroke center post-anesthesia recovery room shall have registered nurses and other essential personnel on call and available within sixty (60) minutes twenty-four (24) hours a day, seven (7) days a week; (I-R, II-R)

2. The stroke center post-anesthesia recovery room's registered nurses shall annually maintain core competencies as required by the stroke center; (I-R, II-R)

3. The stroke center post-anesthesia recovery room shall have at least the following equipment for resuscitation and to provide life support for the stroke patient:

A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen, and mechanical ventilator; (I-R, II-R)

B. Suction devices; (I-R, II-R)

C. Telemetry, ECG capability, cardiac monitor, and defibrillator; (I-R, II-R)

D. All standard intravenous fluids and administration devices, including intravenous catheters; and (I-R, II-R)

E. Drugs and supplies necessary for emergency care; and (I-R, II-R)

4. The stroke center post-anesthesia recovery room shall maintain all equipment according to the hospital preventive maintenance schedule and document when it is checked. (I-R, II-R)

(G) The stroke center shall have clinical laboratory services available twenty-four (24) hours a day, seven (7) days a week that meet the following requirements:

1. Written protocol to provide timely availability of results; (I-R, II-R, III-R, IV-R)

2. Standard analyses of blood, urine, and other body fluids; (I-R, II-R, III-R, IV-R)

3. Blood typing and cross-matching; (I-R, II-R, III-R)

4. Coagulation studies; (I-R, II-R, III-R, IV-R)

5. Comprehensive blood bank or access to a community central blood bank and adequate hospital blood storage facilities; (I-R, II-R, III-R)

6. Blood bank or access to a community central blood bank and adequate hospital blood storage facilities; (IV-R)

7. Blood gases and pH determinations; (I-R, II-R, III-R, IV-R)

8. Blood chemistries; and (I-R, II-R, III-R, IV-R)

9. Written protocol for prioritization of the stroke patient with other time critical patients. (I-R, II-R, III-R, IV-R)

(H) The stroke center shall have support services to assist the patient's family from the time of entry into the facility to the time of discharge and records to document that these services were provided. (I-R, II-R, III-R, IV-R)

(I) The stroke center shall have a stroke rehabilitation program or a plan to refer those stroke patients that require rehabilitation to another facility or community agency that can provide necessary services. (I-R, II-R, III-R)

(4) Continuing Medical Education (CME) and Continuing Education Standards for Stroke Center Designation.

(A) The stroke center shall ensure that staff providing services to stroke patients receives required continuing medical education and continuing education and document this continuing medical education and continuing education for each staff member. The department shall allow up to one (1) year from the date of the hospital's initial stroke center designation for stroke center staff members to complete all of the required continuing medical education and continuing education if the stroke center staff complete and document that at least half of the required continuing medical education and/or continuing education hours have been completed for

each stroke center staff member at the time of on-site initial application review. The stroke center shall submit documentation to the department within one (1) year of the initial designation date that all continuing medical education and continuing education requirements for stroke center staff members have been met in order to maintain the stroke center's designation. (I-R, II-R, III-R, IV-R)

(B) The stroke call roster members shall complete the following continuing education requirements:

1. Level I core team members of the stroke call roster shall complete a minimum of ten (10) hours of continuing education in cerebrovascular disease every year, and it is recommended that a portion of those hours shall be on stroke care. All other members of the stroke call roster in level I stroke centers shall complete a minimum average of ten (10) hours of continuing education in cerebrovascular disease every year. This continuing education shall be reviewed for appropriateness to the practitioner's level of responsibility by the stroke medical director; (I-R)

2. Level II core team members of the stroke call roster shall complete a minimum of eight (8) hours of continuing education in cerebrovascular disease every year, and it is recommended that a portion of those hours be in stroke care. All other members of the stroke call roster in level II stroke centers shall complete a minimum average of eight (8) hours of continuing education in cerebrovascular disease every year. This continuing education shall be reviewed for appropriateness to the practitioner's level of responsibility by the stroke medical director; and (II-R)

3. Level III and IV stroke call roster members shall complete a minimum average of eight (8) hours of continuing education in cerebrovascular disease every two (2) years. This continuing education shall be reviewed for appropriateness to the practitioner's level of responsibility by the stroke medical director. (III-R, IV-R)

(C) The stroke medical director shall complete the following continuing medical education requirements:

1. Level I stroke medical directors shall complete a minimum of twelve (12) hours of continuing medical education every year in the area of cerebrovascular disease; (I-R)

2. Level II stroke medical directors shall complete a minimum of eight (8) hours of continuing medical education every year in the area of cerebrovascular disease; and (II-R)

3. Level III and IV stroke medical directors shall complete a minimum of eight (8) hours of continuing medical education every two (2) years in the area of cerebrovascular disease. (III-R, IV-R)

(D) The stroke center's stroke program manager/coordinator shall complete the following continuing education requirements:

1. Level I program managers/coordinators shall:

A. Complete a minimum of ten (10) hours of continuing education every year in cerebrovascular disease. This continuing education shall be reviewed by the stroke medical director for appropriateness to the stroke program manager/coordinator's level of responsibility; and (I-R)

B. Attend one (1) national, regional, or state meeting every two (2) years focused on the area of cerebrovascular disease. If the national or regional meeting provides continuing education, then that continuing education may count toward the annual requirement; (I-R)

2. Level II program managers/coordinators shall—

A. Complete a minimum average of eight (8) hours of continuing education every year in cerebrovascular disease. This continuing education shall be reviewed for appropriateness by the stroke medical director to the stroke program manager/coordinator's level of responsibility; and (II-R)

B. Attend one (1) national, regional, or state meeting every three (3) years focused on the area of cerebrovascular disease. If the national, regional, or state meeting provides continuing education, then that continuing education may count toward the annual requirement; and (II-R)

3. Level III and IV center program managers/coordinators shall complete a minimum average of eight (8) hours of continuing education in cerebrovascular disease every two (2) years. This continuing education shall be reviewed by the stroke medical director for appropriateness to the stroke program manager/coordinator's level of responsibility. (III-R, IV-R)

(E) Emergency department personnel in stroke centers shall complete the following continuing education requirements:

1. Emergency department physicians in stroke centers shall complete—

A. Level I and II emergency department physicians providing stroke coverage shall complete a minimum average of four (4) hours of continuing medical education in cerebrovascular disease every year; or (I-R, II-R)

B. Level III and IV emergency department physicians providing stroke coverage shall complete a minimum average of six (6) hours of continuing medical education in cerebrovascular disease every two (2) years; and (III-R, IV-R)

2. Registered nurses assigned to the emergency departments in stroke centers shall complete—

A. Level I and II registered nurses shall complete a minimum of four (4) hours of cerebrovascular disease continuing education every year; (I-R, II-R)

B. Level III and IV registered nurses shall complete a minimum of six (6) hours of cerebrovascular disease continuing education every two (2) years; and (III-R, IV-R)

C. Registered nurses shall maintain core competencies in the care of the stroke patient annually as determined by the stroke center. Training to maintain these competencies may count toward continuing education requirements. (I-R, II-R, III-R, IV-R)

(F) Registered nurses assigned to the intensive care unit in the stroke centers who care for stroke patients shall complete the following continuing education requirements:

1. Level I intensive care unit registered nurses shall complete a minimum of ten (10) hours of cerebrovascular related continuing education every year; (I-R)

2. Level II intensive care unit registered nurses shall complete a minimum of eight (8) hours of cerebrovascular related continuing education every year; and (II-R)

3. The stroke medical director shall review the continuing education for appropriateness to the practitioner's level of responsibility. (I-R, II-R)

(G) Stroke unit registered nurses in the stroke centers shall complete the following continuing education requirements:

1. All level I stroke unit registered nurses shall complete a minimum of ten (10) hours of cerebrovascular disease continuing education every year; (I-R)

2. All level II stroke unit registered nurses shall complete a minimum of eight (8) hours of cerebrovascular disease continuing education every year; (II-R)

3. All level III stroke centers caring for stroke patients under an established plan for admitting and caring for stroke patients under a supervised relationship with a physician affiliated with a level I or II stroke center shall require registered nurses in the stroke unit complete a minimum of eight (8) hours of cerebrovascular disease continuing education every two (2) years; and (III-R)

4. The stroke medical director shall review the continuing education for appropriateness to the practitioner's level of responsibility. (I-R, II-R, III-R)

(5) Standards for Hospital Performance Improvement and Patient Safety, Outreach,

Public Education, and Training Programs for Stroke Center Designation.

(A) The stroke center shall maintain an ongoing performance improvement and patient safety program designed to objectively and systematically monitor, review, and evaluate the quality, timeliness, and appropriateness of patient care; resolve problems; and improve patient care. (I-R, II-R, III-R, IV-R)

1. The stroke center shall collect, document, trend, maintain for at least five (5) years, and make available for review by the department at least the following data elements:

A. Door-to-needle time; (I-R, II-R, III-R)

B. Number of patients presenting within the treatment window; and (I-R, II-R, III-R)

C. Number of eligible patients treated with thrombolytics. (I-R, II-R, III-R)

2. The stroke center shall at least quarterly conduct a regular morbidity and mortality review meeting which shall be documented in the meeting minutes and/or the meeting attendance documents. (I-R, II-R, III-R, IV-R)

3. The stroke center shall review the reports generated by the department from the Missouri stroke registry. (I-R, II-R, III-R, IV-R)

4. The stroke center shall conduct monthly reviews of pre-hospital stroke care including inter-facility transfers. (I-R, II-R, III-R, IV-R)

5. The stroke center shall participate in the emergency medical services regional system of stroke care in its respective emergency medical services region as defined in 19 CSR 30-40.302. (I-R, II-R, III-R, IV-R)

6. The stroke center shall document review of its cases of stroke patients who received U.S. Food and Drug Administration-approved thrombolytics and who remained at the referring hospital greater than ninety (90) minutes prior to transfer. (I-R, II-R, III-R)

7. The stroke center shall document its review of cases of stroke patients who did not receive U.S. Food and Drug Administration-approved thrombolytics and who remained greater than sixty (60) minutes at the referring hospital prior to transfer. (II-R, III-R, IV-R)

8. The stroke center shall review and monitor the core competencies of the physicians, practitioners, and nurses and document these core competencies have been met. (I-R, II-R, III-R, IV-R)

(B) The stroke center shall establish a patient and public education program to promote stroke prevention and stroke symptoms awareness. (I-R, II-R, III-R, IV-R)

(C) It is recommended that level I, II, and III stroke centers establish a professional education outreach program in catchment areas to provide training and other supports to improve care of stroke patients. (I-R, II-R, III-R)

(D) Each stroke center shall establish a training program for professionals on caring for stroke patients in the stroke center that includes at least the following:

1. A procedure for training nurses and clinical staff to be credentialed in stroke care; (I-R, II-R, III-R, IV-R)

2. A mechanism to assure that all nurses providing care to stroke patients complete a minimum of required continuing education as set forth in section (4) of this rule to become credentialed in stroke care; and (I-R, II-R, III-R, IV-R)

3. The content and format of any stroke continuing education courses developed and offered by the stroke center shall be developed with the oversight of the stroke medical director. (I-R, II-R, III-R, IV-R)

(E) The stroke center shall provide and monitor timely feedback to the emergency medical service providers and referring hospital, if involved. This feedback shall include, at least, diagnosis, treatment, and disposition of the patients. It is recommended that the feedback be provided within seventy-two (72) hours of admission to the hospital. When emergency medical services does not provide patient care data on patient arrival or in a timely fashion (recommended within three (3) hours of patient delivery), this time frame shall not apply. (I-R, II-R, III-R, IV-R)

(F) Stroke centers shall be actively involved in local and regional emergency medical services systems by providing training and clinical educational resources. (I-R, II-R, III-R, IV-R)

(6) Standards for the Programs in Stroke Research for Stroke Center Designation.

(A) Level I stroke centers shall support an ongoing stroke research program as evidenced by any of the following:

1. Production of evidence-based reviews of the stroke program's process and clinical outcomes; (I-R)

2. Publications in peer-reviewed journals; (I-R)

3. Reports of findings presented at regional, state, or national meetings; (I-R)

4. Receipt of grants for study of stroke care; (I-R)

5. Participation in multi-center studies; and (I-R)

6. Epidemiological studies and individual case studies. (I-R)

(B) The stroke center shall agree to cooperate and participate with the department in developing stroke prevention programs. (I-R, II-R, III-R, IV-R)

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.740 Definitions and Abbreviations Relating to ST-Segment Elevation Myocardial Infarction (STEMI) Centers

PURPOSE: This rule defines terminology related to STEMI centers.

(1) For the purposes of 19 CSR 30-40.750 and 19 CSR 30-40.760 the following terms shall mean:

(A) Acute—an injury or illness that happens or appears quickly and can be serious or life-threatening;

(B) Anesthesiologist assistant (AA)—a person who—

1. Has graduated from an anesthesiologist assistant program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation or by its successor agency;

2. Has passed the certifying examination administered by the National Commission on Certification of Anesthesiologist Assistants;

3. Has active certification by the National Commission on Certification of Anesthesiologist Assistants;

4. Is currently licensed as an anesthesiologist assistant in the state of Missouri; and

5. Provides health care services delegated by a licensed anesthesiologist;

(C) Board-admissible/board-eligible—a physician who has applied to a specialty board of the American Board of Medical Specialties, the American Osteopathic Association Board of Osteopathic Specialists, or the Royal College of Physicians and Surgeons of Canada and has received a ruling that he or she has fulfilled the requirements to take the examinations. Board certification is generally obtained within five (5) years of the first appointment;

(D) Board-certified—a physician who has fulfilled all requirements, has satisfactorily completed the written and oral examinations, and has been awarded a board diploma in a specialty field by the American Board of Medical Specialties, the American Osteopathic Association Board of Osteopathic

Specialists, or the Royal College of Physicians and Surgeons of Canada;

(E) Cardiac catheterization laboratory—the setting within the hospital where percutaneous coronary interventions are done. Specialized staff, equipment, and protocol must be in place;

(F) Cardiac catheterization team—physicians and clinical staff who perform percutaneous coronary interventions and who are part of the clinical STEMI team;

(G) Cardiogenic shock—a life threatening condition in which the heart muscle does not pump enough blood to meet the body's needs;

(H) Cardiologist—a licensed physician with appropriate specialty training;

(I) Cardiology Service—an organizational component of the hospital specializing in the care of patients who have had STEMIs or some other cardiovascular condition or disorder;

(J) Catchment area—the surrounding area served by the institution (the STEMI center);

(K) Certified registered nurse anesthetist (CRNA)—a registered nurse who—

1. Has graduated from a school of nurse anesthesia accredited by the Council on Accreditation of Educational Programs of Nurse Anesthesia or its predecessor;

2. Has been certified as a nurse anesthetist by the Council on Certification of Nurse Anesthetists; and

3. Has been licensed in Missouri pursuant to Chapter 335, RSMo;

(L) Clinical staff—an individual that has specific training and experience in the treatment and management of STEMI patients. Examples include physicians, registered nurses, advanced practice nurses, physician assistants, pharmacists, and technologists;

(M) Clinical team—a team of health care professionals involved in the care of the STEMI patient and may include, but not be limited to, cardiologists, interventional cardiologists, cardiovascular surgeons, anesthesiologists, emergency medicine, and other STEMI center clinical staff. The clinical team is part of the hospital's STEMI team;

(N) Contiguous leads—the electrical cables that attach the electrodes on the patient to the electrocardiograph recorder and which are next to one another. They view the same general area of the heart;

(O) Continuing education—education approved or recognized by a national and/or state professional organization and/or STEMI medical director;

(P) Continuing medical education (CME)—the highest level of continuing education for physicians that is approved by a national and/or state professional organization and/or STEMI medical director;

(Q) Core team—a subunit of the hospital STEMI team which consists of a physician experienced in diagnosing and treating STEMI (usually the STEMI medical director) and at least one (1) other health care professional or qualified individual competent in STEMI care as determined by the hospital (usually the STEMI program manager/coordinator);

(R) Credentialed or credentialing—a hospital-specific system of documenting and recognizing the qualifications of medical staff and nurses and authorizing the performance of certain procedures and establishing clinical privileges in the hospital setting;

(S) Department—the Missouri Department of Health and Senior Services;

(T) Door-to-balloon-time—the time from arrival at the hospital door to percutaneous coronary intervention balloon inflation for the purpose of restoring blood flow in an obstructed coronary artery in the cardiac catheterization lab. This term is commonly abbreviated as D2B;

(U) Door-to-device-time—the time from patient arrival at the hospital to the time the device is in the affected cardiac blood vessel;

(V) Door-to-needle-time—the time from arrival at the hospital door to initiation of lytic therapy to restore blood flow in an obstructed blood vessel;

(W) Electrocardiogram (ECG/EKG)—a recorded tracing of the electrical activity of the heart. The heart rate, heartbeat regularity, size and chamber position, presence of any prior heart attack, current injury, and the effects of drugs or devices (i.e., pacemaker can be determined). An abnormal ECG pattern is seen during a heart attack because damaged areas of the heart muscle do not conduct electricity properly;

(X) Emergency medical service regions—the six (6) regions in the state of Missouri which are defined in 19 CSR 30-40.302;

(Y) First medical contact—a patient's initial contact with a health-care provider either pre-hospital, which could be contact with emergency medical service personnel or another medical provider, or in the hospital;

(Z) First medical contact to balloon or device time—the time from a patient's first medical contact with a health-care provider to the time when the balloon is inflated or the device is in the affected cardiac blood vessel;

(AA) First medical contact to hospital door time—the time from a patient's first medical contact with a health-care provider to the time when the patient arrives at the hospital door;

(BB) Hospital—an establishment as defined by section 197.020.2, RSMo, or a hospital operated by the state;

(CC) Immediately available (IA)—being present at bedside at the time of the patient's arrival at the hospital when prior notification is possible and no more than twenty (20) minutes from the hospital under normal driving and weather conditions;

(DD) In-house (IH)—being on the hospital premises twenty-four (24) hours a day;

(EE) Intermediate care unit—the functional division or facility of the hospital that provides care for STEMI patients admitted to the STEMI center;

(FF) Interventional cardiologist—a licensed cardiologist with the appropriate specialty training;

(GG) Lytic therapy (fibrinolysis/thrombolysis)—drug therapy used to dissolve clots blocking flow in a blood vessel. It refers to drugs used for that purpose, including recombinant tissue plasminogen activator. This type of therapy can be used in the treatment of acute ischemic stroke and acute myocardial infarction;

(HH) Mentoring relationship—a relationship in which a high volume percutaneous coronary interventions operator, often described as performing one hundred fifty (150) or more procedures per year, serves as a mentor for an operator who performs less than eleven (11) primary percutaneous coronary interventions per year;

(II) Missouri STEMI registry—a statewide data collection system comprised of key data elements as identified by the Department of Health and Senior Services used to compile and trend statistics of STEMI patients both pre-hospital and hospital, using a coordinated electronic reporting method provided by the Missouri Department of Health and Senior Services;

(JJ) Multidisciplinary team—a team of appropriate representatives of hospital units involved in the care of the STEMI patient. This team supports the care of the STEMI patient with the STEMI team;

(KK) Patient—an individual who is sick, injured, wounded, diseased, or otherwise incapacitated or helpless, or dead, excluding deceased individuals being transported from or between private or public institutions, homes, or cemeteries, and individuals declared dead prior to the time an ambulance is called for assistance;

(LL) Peer review system—is the process the STEMI center establishes for physicians to review STEMI cases on patients that are admitted to the STEMI center, transferred out of the STEMI center, or die as a result of

the STEMI (independent of hospital admission or hospital transfer status);

(MM) Percutaneous coronary intervention (PCI)—is a procedure used to open or widen narrowed or blocked blood vessels to restore blood flow supplying the heart. A primary percutaneous coronary intervention is one that is generally done on an emergency basis for a ST-elevation myocardial infarction (STEMI). Treatment occurs while the blood clot is still forming—usually within twenty-four (24) hours of onset, but ideally within two (2) hours of symptoms onset. An elective percutaneous coronary intervention is one that is done on a non-urgent basis to reduce signs and symptoms of angina;

(NN) Percutaneous coronary intervention window—the time frame in which percutaneous coronary intervention is most advantageous and recommended;

(OO) Phase I cardiac rehabilitation—an inpatient program that provides an individualized exercise and education plan for patients with cardiac illnesses;

(PP) Physician—a person licensed as a physician pursuant to Chapter 334, RSMo;

(QQ) Promptly available (PA)—arrival at the hospital at the patient's bedside within thirty (30) minutes after notification of a patient's arrival at the hospital;

(RR) Protocol—a predetermined, written medical care guideline, which may include standing orders;

(SS) Qualified individual—a physician, registered nurse, advanced practice registered nurse, and/or physician assistant that demonstrates administrative ability and shows evidence of educational preparation and clinical experience in the care of STEMI patients and is licensed by the state of Missouri;

(TT) Regional outcome data—data used to assess the regional process for pre-hospital, hospital, and regional patient outcomes;

(UU) Repatriation—the process used to return a STEMI patient to his or her home community from a level I or level II STEMI designated hospital after his or her acute treatment for STEMI has been completed. This allows the patient to be closer to home for continued hospitalization or rehabilitation and follow-up care as indicated by the patient's condition;

(VV) Reperfusion—the process of restoring normal blood flow to an organ or tissue that has had its blood supply cut off, such as after an ischemic stroke or myocardial infarction;

(WW) Requirement (R)—a symbol to indicate that a standard is a requirement for STEMI center designation at a particular level;

(XX) Review—is the inspection of a hospital to determine compliance with the rules of this chapter;

(YY) ST-elevation myocardial infarction (STEMI)—a myocardial infarction for which the electrocardiogram shows ST-segment elevation, usually in association with an acutely blocked coronary artery. A STEMI is one type of heart attack that is a potentially lethal condition for which specific therapies, administered rapidly, reduce mortality and disability. The more time that passes before blood flow is restored, the more damage that is done to the heart muscle;

(ZZ) STEMI call roster—a schedule that provides twenty-four (24) hours a day, seven (7) days a week cardiology service coverage. The call roster identifies the physicians or qualified individuals on the schedule that are available to manage and coordinate emergent, urgent, and routine assessment, diagnosis, and treatment of the STEMI patients;

(AAA) STEMI care—education, prevention, emergency transport, triage, acute care, and rehabilitative services for STEMI that requires immediate medical or surgical intervention or treatment;

(BBB) STEMI center—a hospital that is currently designated as such by the department to care for patients with ST-segment elevation myocardial infarctions.

1. A level I STEMI center is a receiving center staffed and equipped to provide total care for every aspect of STEMI care, including care for those patients with complications. It functions as a resource center for the hospitals within that region and conducts research.

2. A level II STEMI center is a receiving center staffed and equipped to provide care for a large number of STEMI patients within the region.

3. A level III STEMI center is primarily a referral center that provides prompt assessment, indicated resuscitation, and appropriate emergency intervention for STEMI patients to stabilize and arrange timely transfer to a Level I or II STEMI center, as needed.

4. A level IV STEMI center is a referral center in an area considered rural or where there are insufficient hospital resources to serve the patient population requiring STEMI care. The level IV STEMI center provides prompt assessment, indicated resuscitation, appropriate emergency intervention, and arranges and expedites transfer to a higher level STEMI center as needed;

(CCC) STEMI identification—a diagnosis is made on a basis of symptoms, clinical examination, and electrocardiogram changes, specifically ST-segment elevation;

(DDD) STEMI medical director—a physician designated by the hospital who is responsible for the STEMI service and performance improvement and patient safety programs related to STEMI care;

(EEE) STEMI program—an organizational component of the hospital specializing in the care of STEMI patients;

(FFF) STEMI program manager—a qualified individual designated by the hospital with responsibility for monitoring and evaluating the care of STEMI patients and the coordination of performance improvement and patient safety programs for the STEMI center in conjunction with the physician in charge of STEMI care;

(GGG) STEMI team—a component of the hospital STEMI program which consists of the core team and the clinical team;

(HHH) Symptom onset-to-treatment time—the time from symptom onset to initiation of therapy to restore blood flow in an obstructed blood vessel;

(III) Thrombolytics—drugs, including recombinant tissue plasminogen activator, used to dissolve clots blocking flow in a blood vessel. These thrombolytic drugs are used in the treatment of acute ischemic stroke and acute myocardial infarction; and

(JJJ) Transfer agreement—a document which sets forth the rights and responsibilities of two (2) hospitals regarding the inter-hospital transfer of patients.

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.750 ST-Segment Elevation Myocardial Infarction (STEMI) Center Designation Application and Review

PURPOSE: This rule establishes the requirements for participation in Missouri's STEMI center program.

(1) Participation in Missouri's STEMI center program is voluntary and no hospital shall be required to participate. No hospital shall hold itself out to the public as a state-designated STEMI center unless it is designated as such by the Department of Health and Senior Services (department). Hospitals desiring STEMI center designation shall apply to the department. Only those hospitals found by review to be in compliance with the requirements of the rules of this chapter shall be designated by the department as STEMI centers.